DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 1 1 2012

Cosmed S.R.L.
C/O Mr. Thomas Padula
Vice President, Regulatory Compliance
Schiff & Company, Incorporated
1129 Bloomfield Avenue
WEST CALDWELL NJ 07006

Re: K120146
Trade/Device Name: Quark Series
Regulation Number: 21 CFR 868.1890
Regulation Name: Predictive Pulmonary-Function Value Calculator
Regulatory Class: II
Product Code: CBK, BTY
Dated: November 15, 2012
Received: November 16, 2012

Dear Mr. Padula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use statement

510(k) Number: K120146

Device Name: Quark Series

Generic Indication for use (for all models)

The COSMED Quark Series system is a modular system with multiple configurations, allowing the following measurements: Spirometry, Lung Function Testing, Cardiopulmonary Exercise Testing, Resting Metabolism.

The system and its accessories are indicated for the acquisition, analysis, formatting, display, printing and storage of certain physiologic signals. It is intended to assist a clinician in the diagnosis of cardio-pulmonary disease conditions.

Specific Indications for use

Device model	Indication for use	Major clinical conditions	Measured parameters
Quark SPIRO	Pulmonary Function testing - Age 6 to adults	Spontaneously breathing patients, healthy or affected by respiratory diseases such as asthma or COPD	FVC, FEV1, FEF25-75%, PEF, MVV, SpO_2
Quark PFT	Pulmonary Function testing - Age 6 to adults Cardiopulmonary Exercise testing – age 6 to adults	Spontaneously breathing patients, healthy or affected by respiratory diseases such as asthma or COPD	FVC, FEV1, FEF25-75%, PEF, MVV, FRC, DLCO, MIP/MEP, P0.1, SpO_2, Ve, RF, HR, VO_2, VCO_2, TGV
Quark CPET	Pulmonary Function testing - Age 6 to adults Cardiopulmonary Exercise testing – age 6 to adults	Spontaneously breathing patients, healthy or affected by diseases limiting exercise tolerance	FVC, FEV1, FEF25-75%, PEF, MVV, VO_2, VCO_2, Ve, RF, HR, SpO_2
Quark RMR	Measurement of Resting Metabolism (face mask) – age 6 to adults; Measurement of Resting Metabolism (canopy dilution) –15Kg/30Lb to adults; Measurement of Resting Metabolism (Ventilated patients) – age 10 to adults	Spontaneously breathing patients; Ventilated patients with some limitations as in accordance with labeling	VO_2, VCO_2, Ve, RF, HR, SpO_2

Quark SPIRO and Quark PFT also allows the Airways Resistance Test with the occlusion technique (R_{occ} test) for young patients from 3 to 6 years old.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120146

Prescription use_____ Over-the-Counter Use_____
(Per 21 CFR 801.109) (Optional format 1-2-96)